

**REPORT OF THE
QUALITY AND PATIENT SAFETY COMMITTEE OF THE
BOARD OF DIRECTORS OF THE
COOK COUNTY HEALTH AND HOSPITALS SYSTEM**

JANUARY 27, 2009

ATTENDANCE

Present: Chairman David Ansell, MD and Luis Muñoz, MD, MPH (2)

Lois Elia and Pat Merriweather (Non-Director Members)

Absent: Director Hon. Jerry Butler (1)

Also Present: Homer Abiad, MD – President of the Medical Staff, Oak Forest Hospital of Cook County; David Barker, MD - ____; Janice Benson, MD – President of the Medical Staff, John H. Stroger, Jr. Hospital of Cook County; Julie Bonello – Chief Information Officer, Cook County Health and Hospitals System; Martina Harrison, RN, MSN – MSN, Chief Nursing Officer, Provident Hospital; Aaron Hamb, Chief Medical Officer, Provident Hospital of Cook County; Avery Hart, MD – Interim Chief Medical Officer, Cermak Health Services; Catherine Kelly – Office of the State's Attorney; Sue Klein – Director of Quality, John H. Stroger, Jr. Hospital of Cook County; Mark Krause, MD – President of the Medical Staff, Provident Hospital of Cook County; Maurice Lemon, MD, MPH – Chief Medical Officer, John H. Stroger, Jr. Hospital of Cook County; Charlene Luchsinger – Credentials Verification Officer, Cook County Health and Hospitals System; Stephen Martin, PhD, MPH – Chief Operating Officer, Cook County Department of Public Health; Enrique Martinez, MD – Chief Medical Officer, Ambulatory and Community Health Network of Cook County; Lula Roberson – Interim Director, Quality Services, Provident Hospital of Cook County; Deborah Santana – Office of the Secretary to the Board of Commissioners of Cook County; Angela Schrimpl – Director of Accreditation and Quality, Ambulatory and Community Health Network of Cook County

Ladies and Gentlemen:

Your Quality and Patient Safety Committee of the Board of Directors of the Cook County Health and Hospitals System met pursuant to notice on Tuesday, January 27, 2009 at the hour of 12:00 P.M. at Stroger Hospital, 1901 West Harrison Street, in the fifth floor conference room, in Chicago, Illinois.

Your Quality and Patient Safety Committee has considered the following items and, upon adoption of this report, the recommendations follow.

Welcome and Introductions

Chairman Ansell welcomed the attendees and asked all present at the meeting to introduce themselves. Additionally, he introduced a new non-Director member, Lois Elia, whom Chairman Batts has appointed to serve on the Committee in place of Dr. Lee Sacks. Dr. Sacks has had scheduling difficulties and has been unable to attend the meetings.

Roll Call

Deborah Santana, of the Office of the Secretary to the Board, called the roll of members, and it was determined that a quorum was present.

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Review and accept minutes of the following meetings:

- Meeting of November 25, 2008 (deferred on 12/23/08)
- Meeting of December 23, 2008

Director Muñoz, seconded by Chairman Ansell, moved to accept the minutes of the meetings of the Quality and Patient Safety Committee of November 25, 2008 and December 23, 2008. **THE MOTION CARRIED UNANIMOUSLY.**

Receive update on Family Case Management Transition

Dr. Stephen Martin, Chief Operating Officer of the Cook County Department of Public Health, presented an update on the Family Case Management Program transition. (See Attachment #1.)

Review and recommend approval of Institutional Review Board Use Agreement between the Board of Trustees of the University of Illinois and Cook County/Cook County Health and Hospitals System (Attachment #2)

Director Muñoz, seconded by Chairman Ansell, moved to recommend the approval of the Institutional Review Board Use Agreement between the Board of Trustees of the University of Illinois and Cook County/Cook County Health and Hospitals System. **THE MOTION CARRIED UNANIMOUSLY.**

Progress on Dashboard

Chairman Ansell distributed materials that provided information on some ideas for dashboard reporting. He noted that not only does the System need to meet standards, they also have to demonstrate improvement.

Ms. Elia provided information on the dashboard structure at Advocate, at the request of Chairman Ansell.

The Committee discussed the information. Chairman Ansell stated that at the next meeting, he would like to see on the "idea level" what should be on a System-wide dashboard.

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Receive quarterly quality report and report on status of preparations from Cermak Health Services

Receive report on provisional status of Ambulatory and Community Health Network accreditation by Joint Commission

Receive and approve Medical Staff Appointments/Re-appointments/Changes

Receive report of the Joint Conference Committee of Stroger Hospital for the meeting of November 18, 2008

Receive reports from the Medical Staff Executive Committees from Provident, Oak Forest and Stroger Hospitals

Receive reports on the following:

- Any Sentinel Events or Near Misses
- Any Patient Grievance Reports
- Update on “never” events
- Report on Recent Regulatory Visits

Director Muñoz, seconded by Chairman Ansell, moved to recess the regular session and convene into closed session, pursuant to an exception to the Illinois Open Meetings Act, 5 ILCS 120/2(c)(17), et seq., which permits closed meetings for consideration of “the recruitment, credentialing, discipline or formal peer review of physicians or other health care professionals for a hospital, or other institution providing medical care, that is operated by the public body,” and pursuant to an exception to the Open Meetings Act, 5 ILCS 120/2(c)(11), which states: “litigation, when an action against, affecting or on behalf of the particular body has been filed and is pending before a court or administrative tribunal, or when the public body finds that an action is probable or imminent, in which case the basis for the finding shall be recorded and entered into the minutes of the closed meeting.” THE MOTION CARRIED UNANIMOUSLY.

Chairman Ansell, seconded by Director Muñoz, moved to adjourn the closed session and convene into regular session. THE MOTION CARRIED UNANIMOUSLY.

Chairman Ansell, seconded by Director Muñoz, moved to approve the Medical Staff Appointments/Re-appointments/Changes. THE MOTION CARRIED UNANIMOUSLY.

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Following are the Medical Staff Appointments/Re-appointments/Changes that were approved:

JOHN H. STROGER, JR. HOSPITAL OF COOK COUNTY

INITIAL APPOINTMENTS

Physicians:

Bonaparte, Katina, M.D. Appointment Effective:	Cermak/Med/Surg January 27, 2009 through January 26, 2011	Active Physician
Davis, Vanessa, M.D. Appointment Effective:	Pediatrics/Endocrinology January 27, 2009 through January 26, 2011	Active Physician
Harting, Brian, M.D. Appointment Effective:	Medicine/Infectious Diseases January 27, 2009 through January 26, 2011	Voluntary Physician
Weber, Thomas, M.D. Appointment Effective:	Surgery/General Surgery January 27, 2009 through January 26, 2011	Voluntary Physician

Mid Level Practitioner:

Brown, Nikki, A., PA-C Appointment Effective:	Emergency Medicine January 27, 2009 through January 26, 2011	Physician Assistant
Nosheen, Uzma, PA-C Appointment Effective:	Emergency Medicine January 27, 2009 through January 26, 2011	Physician Assistant

REAPPOINTMENT APPLICATIONS

Physicians:

Correctional Center Health Services

Lee, Choong H., M.D. Reappointment Effective:	Psychiatry April 17, 2009 through April 16, 2011	Voluntary Physician
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Department of Medicine

Goodman, Larry, M.D. Reappointment Effective:	Infectious Disease January 27, 2009 through January 26, 2011	Voluntary Physician
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Department of Surgery

Chaudhry, Vivek, M.D. Reappointment Effective:	Surgery/Colon & Rectal February 19, 2009 through February 18, 2011	Active Physician
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JOHN H. STROGER, JR. HOSPITAL OF COOK COUNTY (continued)

Mid Level Practitioner Reappointments:

Argueta, Alejandra, PA-C Reappointment Effective:	Emergency Medicine January 22, 2009 through January 21, 2011	Physician Assistant
Flucker, Venita R., PA-C Reappointment Effective:	Obstetrics & Gynecology January 22, 2009 through January 21, 2011	Physician Assistant
Micci, Sandra J., PA-C Reappointment Effective:	Medicine January 27, 2009 through January 26, 2011	Physician Assistant
Shah, Palak K., PA-C Reappointment Effective:	Surgery January 27, 2009 through January 26, 2011	Physician Assistant
Soriano, Alexandra, PA-C Reappointment Effective:	Emergency Medicine January 27, 2009 through January 26, 2011	Physician Assistant

Collaborative Agreement

Nosheen, Uzma, PA-C	Emergency Medicine	Physician Assistant
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Collaborative Agreement with Prescriptive Authority

Argueta, Alejandra, PA-C	Emergency Medicine	Physician Assistant
Brown, Nikki, A., PA-C	Emergency Medicine	Physician Assistant
Flucker, Venita R., PA-C	Obstetrics & Gynecology	Physician Assistant
Micci, Sandra J., PA-C	Medicine	Physician Assistant
Shah, Palak K., PA-C	Surgery	Physician Assistant
Soriano, Alexandra, PA-C	Emergency Medicine	Physician Assistant

MEDICAL STAFF CHANGE W/NO CHANGE IN CLINICAL PRIVILEGES

Asbury, Joseph, M.D. Medicine/Gen. Med	From Active Physician Grade K7, Step 5 to Active Physician Grade K8, Step 4 Acct # 110, Budget# 8972332; PID # 9621875
Dworkin, Mark, M.D. Medicine/Inf. Disease	From Voluntary Physician to Consultant Physician Grade ZZ; Acct # 133 Budget# 8940701; PID # 0789401
Greager, John, M.D. Surgery/Surgical Onc.	From Active Physician to Voluntary Physician
Jacobs, Elizabeth, M.D. Medicine/Gen. Med	From Active Physician Grade K7, Step 5 to Active Physician Grade K8, Step 4 Acct # 110, Budget# 8970162; PID # 9821890
Kumapley, Rudolph, M.D. Medicine/Gen. Med	From Active Physician Grade K8, Step 4 to Active Physician Grade K9, Step 2 Acct # 110, Budget# 8970170; PID # 0400264

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JOHN H. STROGER, JR. HOSPITAL OF COOK COUNTY

MEDICAL STAFF CHANGE W/NO CHANGE IN CLINICAL PRIVILEGES (continued)

Mayefsky, Jay, M.D. ACHN	From Active Physician Grade K6, Step 5 to Active Physician Grade K7, Step 4 Acct # 110, Budget# 8930418; PID # 700088
Prasad, Leela, M.D. Surgery/Colon Rectal	From Active Physician to Voluntary Physician
Sturman, Maureen, M.D. Medicine/Gen. Med	From Active Physician Grade K7, Step 3 to Medical Div. Chair Grade K7, Step 5, Acct # 110, Budget# 8970162; PID # 9521959

OAK FOREST HOSPITAL OF COOK COUNTY

MEDICAL STAFF INITIAL APPOINTMENTS

<u>Name</u>	<u>Department</u>	<u>Status</u>
Ross-Douglas, Brandi, M.D. Appointment effective Jan. 27, 2009 through Jan. 26, 2011	Medicine/ICU	Visiting Consultant

MEDICAL STAFF REAPPOINTMENTS

<u>Name</u>	<u>Department</u>	<u>Status</u>
Abiad, Homer, M.D. Appointment effective Jan. 27, 2009 Through Jan. 26, 2011	Medicine/Infectious Disease	Active
Adkins, Linda, O.D. Appointment effective Jan. 27, 2009 Through Jan. 26, 2011	Surgery/Optomety	Active
Morcos, Isaac, M.D. Appointment effective Jan. 27, 2009 Through Jan. 26, 2011	Medicine	Visiting Consultant
Gragasin, Maria Elena, M.D. Appointment effective Jan. 27, 2009 Through Jan. 26, 2011	Neurosciences/Neurology	Visiting Consultant

MEDICAL STAFF STATUS CHANGE – Provisional to Active

Patel, Shilpa, M.D.	Medicine/Infectious Disease	Active
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PROVIDENT HOSPITAL OF COOK COUNTY

MEDICAL STAFF APPOINTMENTS

Department of Family Medicine

Ayala, Jose, M.D.	Family Medicine	Affiliate Physician
Appointment effective:	January 27, 2009 through January 26, 2011	

Shah, Ravi, M.D.	Family Medicine	Affiliate Physician
Appointment effective:	January 27, 2009 through January 26, 2011	

Department of Internal Medicine

Tracy, Mark, M.D.	Medicine (PM&R)	Voluntary Physician
Appointment effective:	January 27, 2009 through January 26, 2011	

MEDICAL STAFF REAPPOINTMENTS

Department of Pediatrics

Chinwuba, Ebele M.D.	Pediatrics	Ancillary Physician
Reappointment effective:	November 14, 2008 through November 13, 2010	

Department of Critical Care

Sobek, Sabine, M.D.	Critical Care	Ancillary Physician
Reappointment effective:	February 4, 2009 through February 3, 2011	

MID-LEVEL PRACTITIONER REAPPOINTMENTS

Wyatt, Laura, PA-C	Surgery	Physician Assistant, Certified
Reappointment effective:	January 23, 2009 through January 22, 2011	

Shah, Chandrika, PA-C	Surgery	Physician Assistant, Certified
Reappointment effective:	October 17, 2008 through October 16, 2010	

Diallo, Reneau, CNM, APN	OB/GYN	Certified Nurse Midwife
Reappointment effective:	February 21, 2009 through February 20, 2011	

Schlaegar, Judith, CNM, APN	OB/GYN	Certified Nurse Midwife
Reappointment effective:	February 21, 2009 through February 20, 2011	

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PROVIDENT HOSPITAL OF COOK COUNTY (continued)

MEDICAL STAFF APPOINTMENTS TO BE AMENDED
FROM PROVISIONAL TO FULL STATUS

<u>Name</u>	<u>Department</u>	<u>Status</u>
Leak, Angel., M.D.	Internal Medicine	Active Physician
Date on staff June 17, 2008;	Appointment effective	January 27, 2009
Nadeem, Ahmed, M.D.	Emergency Medicine	Active Physician
Date on staff June 17, 2008;	Appointment effective	January 27, 2009

MEDICAL STAFF CHANGE OF CATEGORY STATUS

Gandhi, Prafull, M.D.	Internal Medicine	Active to Affiliate Physician
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Public Comments

Chairman Ansell asked the Secretary to call upon the registered speakers.

Ms. Santana replied that there were none.

Adjournment


Chairman Ansell, seconded by Director Muñoz, moved to adjourn. THE MOTION CARRIED AND THE MEETING WAS ADJOURNED.

Respectfully submitted,
Quality and Patient Safety Committee of the
Board of Directors of the
Cook County Health and Hospitals System



David Ansell, MD, Chairman

Attest:



Matthew B. DeLeon, Secretary

Cook County Health and Hospitals System
Report of the Meeting of the Quality and Patient Safety Committee
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ATTACHMENT #1

Cook County Department of Public Health

Cook County Health & Hospitals System

(formerly Cook County Bureau of Health Services)

Todd H. Stroger • President
Cook County Board of Commissioners

Warren L. Batts • Chairman
Cook County Health & Hospitals System

Jorge Ramirez • Vice Chairman
Cook County Health & Hospitals System

David R. Small, FACHE • Interim CEO
Cook County Health & Hospitals System



Health System Board Members

Dr. David A. Ansell
Commissioner Jerry Butler
David N. Carvalho
Quin R. Golden
Benn Greenspan
Sr. Sheila Lyne
Dr. Luis R. Muñoz
Heather E. O'Donnell
Andrea L. Zopp

1010 Lake Street, Suite 300
Oak Park, Illinois 60301

Telephone (708) 492-2000
TDD (708) 492-2002

Stephen A. Martin, Jr., Ph.D., M.P.H.
Chief Operating Officer

MEMORANDUM

DATE: JANUARY 27, 2009
TO: DAVID ANSELL, M.D. (QUALITY AND COMPLIANCE COMMITTEE CHAIRMAN)
CC: QUALITY AND COMPLIANCE COMMITTEE OF THE COOK COUNTY HEALTH AND HOSPITALS
SYSTEM BOARD OF DIRECTORS
DAVID SMALL (COO)
FROM: DR. STEPHEN MARTIN
RE: CCDPH CASE MANAGEMENT PROGRAM SERVICE REDUCTION UPDATE REPORT

Below please find an update on the case management program service reduction initiative:

Family Case Management (FCM) Program Transfer Status

- CCDPH continues prenatal intake including WIC certification, enrollment in Medicaid Presumptive Eligibility (MPE), completion of 707G (IDHS) prenatal risk assessment, referral to prenatal care providers, and referral to FCM agency based on zip codes provided by Illinois Department of Human Services (IDHS). From November 20, 2008 through January 20, 2009, a total of 393 prenatal intakes were completed.
- CCDPH continues to provide case management services as part of its statutory obligations to clients through the APORS (Adverse Pregnancy Outcome Reporting System)/HRIF (High Risk Infant Follow-up) program. The caseload for APORS/HRIF as of 12/31/2008 was 2270.
- Negotiations are in process with Aunt Martha's Youth Services (AMYS) to co-locate a FCM case manager at selective Health and Hospital System sites. AMYS is assigned several communities in the south suburban region for case management services. In addition to providing FCM services, AMYS will provide enrollment for the All Kids and Illinois Healthy Women programs regardless of the source of the client's primary medical care.



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FIGURE 1. Cook County Department of Public Health

While the Cook County Department of Public Health (CCDPH) has taken the position that the Family Case Management Program (FCM) needs to be transitioned by the Illinois Department of Human Services to community based organizations (CBO's) and federally qualified health centers (FQHC's), case management services will continue to be provided to populations at highest medical risk.

Case Management Programs

The following case management programs will continue to be provided by CCDPH to suburban Cook County residents in state fiscal year (SFY) 09:

- **High Risk Infant Follow-up (HRIF)** - Follow-up of infants identified through APORS (Adverse Pregnancy Outcome Reporting System) including developmental and physical assessment and referral of high risk infants up to two (2) years of age by a public health nurse. This program is restricted to local health departments.
- **Targeted Intensive Prenatal Case Management (TIP)** -- Intensive case management program with incentives for pregnant women in the communities of Bellwood, Harvey, and Maywood.
- **Subsequent Pregnancy Prevention (SPP)** -- Social support service program for adolescents in Harvey and Markham who have had one prior pregnancy with the "goal" to delay a subsequent pregnancy. Program activities include group discussion, home visits, and educational outings.
- **Healthy Families Illinois (HFI)** -- Intensive case management/home visiting program for a small caseload of families identified at high risk for child abuse and/or neglect in the communities of Cicero, Harvey, Maywood, and Robbins. Program is modeled on the national initiative Healthy Families America.
- **Genetics** -- Case management program to ensure that infants/families impacted by genetic conditions receive primary health care, supportive services, screening, and education to reduce the impact. Infants are enrolled in HRIF.
- **Perinatal Hepatitis B** -- Case management program to ensure that infants born to Hepatitis B positive women receive appropriate intervention and vaccination to prevent complications. Infants are enrolled in HRIF.
- **Lead** -- Case management program for lead exposed (poisoned) children identified by the Illinois Department of Public Health to limit the negative effects of elevated lead. Follow-up includes home assessment, education of care providers, referral for primary health care including treatment, developmental assessment and referral for Early Intervention (EI) services, and tracking of blood lead levels to ensure adequate treatment. If the child/infant is under the age of 2 years, they are enrolled in HRIF.
- **Newborn Hearing Screening** -- Case management program to ensure that infants complete the mandated newborn hearing evaluation and infants with abnormal results receive early intervention and treatment. Infants with abnormal screening tests are enrolled in HRIF. Mandated by state statute to be provided by local health departments.
- **Congenital Syphilis** -- Case management services are provided to infants diagnosed with syphilis at birth (suspect or confirmed) to ensure that repeat RPR titers are done, document successful treatment, and provide education regarding syphilis. Infants are enrolled in HRIF.
- **Sudden Infant Death Syndrome (SIDS)** -- Follow-up is provided to families with infants that have died of SIDS (confirmed or suspect) to ensure that family has social support resources, grief counseling, and primary health care. This is a mandated program for local health departments.
- **Healthy Homes (HH)** -- Personalized health education and remediation products are provided to pregnant women and families with children at high risk for asthma and other acute/chronic respiratory conditions within targeted south suburban communities.
- **Teen Pregnancy Primary Prevention (TPP)** -- School based health education program with Hispanic adolescents to promote healthy lifestyle choices and responsible decision making regarding sexual activity.

Cook County Health and Hospitals System
Report of the Meeting of the Quality and Patient Safety Committee
January 27, 2009

ATTACHMENT #2

Cook County Health & Hospitals System

1900 W. Polk Street, Room 220
Chicago, Illinois 60612

627 South Wood Street, Rm. 218 Chicago, Illinois 60612
312-864-0716



Cook County Health & Hospitals System

David Small
Interim-Chief Executive Officer

Lynda Brodsky
Director, Research Affairs

January 13, 2009

To: Maurice Lemon, Medical Director
From: Lynda Brodsky, Research Affairs
Re: IRB Use Agreement with UIC

Enclosed is the IRB use agreement we have discussed several times. As far as I can figure, it has no financial repercussion at all. I read the agreement and, while I think it is overkill, there is nothing I cannot live with.

It has been signed by UIC and by Dr. Giordano. Now it must be signed by you, President Stroger, and, it turns out, David Orr!. Last time we spoke you thought that perhaps Laura Lechowicz could recommend President Stroger sign it without having to go through the Board.

Please let me know if there is anything I can do to facilitate this project.



OFFICE OF THE STATE'S ATTORNEY
COOK COUNTY, ILLINOIS

ANITA ALVAREZ
STATE'S ATTORNEY

500 RICHARD J. DALEY CENTER
CHICAGO, ILLINOIS 60602
AREA 312-603-5440

CATHERINE M. KELLY
Assistant State's Attorney
Transactions And Health Law Section
Direct: 312-603-6634
Fax: 312-603-3000
CKELLY@COOKCOUNTYGOV.COM

December 22, 2008

Lynda Brodsky
Director, Research Affairs
Cook County Health and Hospitals System
Hektoen Building, Room 218
627 S. Wood Street
Chicago, Illinois 60612

Re: IRB Use Agreement with UIC

Dear Lynda:

Enclosed please find three originals of the IRB Use Agreement between The Board of Trustees of the University of Illinois and Cook County/The Cook County Health and Hospitals Systems. The originals have been executed by UIC. Please ensure that all three of the originals are signed by our representatives as well.

Please also find a letter from UIC's attorney requesting that one fully executed original is returned to her at the completion of our process.

Should you have any questions, please feel free to call me.

Very truly yours,
Anita Alvarez
States Attorney of Cook County

Catherine Kelly
By: Catherine M. Kelly

Enclosures

UNIVERSITY OF ILLINOIS
Chicago • Springfield • Urbana-Champaign

Office of University Counsel (MC 225)
405 Administrative Office Building
173 West Polk Street
Chicago, Illinois 60612-7228

December 17, 1008

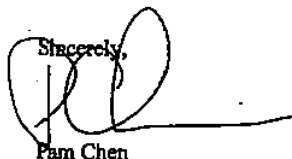
Catherine M. Kelly
Assistant State's Attorney
Transactions & Health Law Section
Cook County State's Attorney Office
100 Daley Center
Chicago, IL 60602

Re: IRB Use Agreement

Dear Cathy,

Enclosed please find three originals of the IRB Use Agreement between The Board of Trustees of the University of Illinois and Cook County, as executed by the University. Once these agreements have been executed by the Cook County, please return one fully executed original to my attention. Thank You.

Sincerely,



Pam Chen

IRB USE AGREEMENT

The Board of Trustees of the University of Illinois And COOK COUNTY

This Institutional Review Board Use Agreement (this "Agreement"), effective on the date last signed below ("Effective Date"), between the County of Cook, Illinois, a body politic and corporate, (hereinafter "County") through its Cook County Health and Hospitals System (hereinafter "System") and The Board of Trustees of the University of Illinois (the "University"), on behalf of the University of Illinois at Chicago ("UIC"), sets forth the terms and conditions under which County may utilize Institutional Review Board #3 at UIC ("UIC IRB") as the local institutional review board of record providing facilitated review for Children's Oncology Group ("COG") clinical research studies being conducted at County using human research subjects approved by the National Cancer Institute's Pediatric Central Institutional Review Board ("NCI IRB").

I. OPERATIONS

1. **Term.** The term of this Agreement shall be for a period of one (1) year ("Initial Term") from the Effective Date, unless earlier terminated as provided herein. Thereafter, this Agreement shall automatically renew for successive one (1) year terms unless notice to terminate is provided no less than ninety (90) days before the end of the Initial Term. At any time subsequent to the Initial Term, the parties shall each have the right to terminate this Agreement without cause and without penalty upon thirty (30) days prior written notice.
2. **IRB Management.** The UIC IRB is administered by the Office for the Protection of Research Subjects at UIC ("OPRS"). The Director of OPRS shall be County's point of contact with respect to the performance of this Agreement by the University. Lisa Giordano, M.D., her designee or her appointed successor shall be the University's point of contact with respect to the performance of this Agreement by County.
3. **Review Criteria.** The UIC IRB shall serve as the local IRB of Record for COG clinical research studies using human research subjects approved by the NCI IRB performed by County employees at County (the "Research"). The UIC IRB shall provide facilitated review of such Research as County may submit under this Agreement to assure compliance with all applicable state and local laws, and also the human subjects' policies and procedures of County, including requirements set forth by County's Office of Human Research Protections ("OHRP") approved Federalwide Assurance ("FWA"), applicable to the Research. County acknowledges and agrees that subsequent to any Research being reviewed and approved by the UIC IRB, if the applicable institutional review board of County reviewing the Research (the "County IRB") modifies any aspect of such Research prior to its commencement at County, such modifications shall be submitted to the UIC IRB for review and approval prior to its commencement. The University shall maintain a Federalwide Assurance with OHRP with respect to the UIC IRB.

4. **Compliance.** County shall be responsible for ensuring the safe and appropriate performance of the Research and the protection of human research subjects at County. This includes, but is not limited to, monitoring the performance of any Research at County, causing County's principal investigators and other research personnel to abide by UIC IRB's decisions and authority with respect to such Research as well as compliance with County's OHRP approved FWA, applicable federal, state and local laws and regulations, including, but not limited to the "The Standards for Privacy of Individual Identifiable Health Information" (45 CFR Parts 160, 162 and 164) regulations ("HIPAA Regulations"), and immediately reporting to UIC IRB of any protocol violations or serious adverse events with respect to such Research. County will designate the UIC IRB on its OHRP approved FWA. County shall provide a copy of its "Research Conduct Policy" and any other applicable policies related to human subject research at County, and any amendments thereto, to the UIC IRB and County Principal Investigators. The University shall comply with the terms of the University's OHRP approved FWA for the UIC IRB and applicable federal and state laws, rules and regulations, including, but not limited to, HIPAA regulations.
5. **Meeting Minutes.** Portions of the minutes of the UIC IRB meetings relevant or applicable to the Research will be made available to County upon request. Portions of the minutes of the County IRB meetings relevant or applicable to the Research will be made available to UIC upon request.
6. **Confidentiality.** Except to the extent disclosure is compelled by law, for example, under the U.S. or Illinois Freedom of Information Act, or by judicial process, all meeting minutes, protocols, OPRS files, IRB work product and correspondences and any materials marked "Confidential" and other related materials disclosed by one party to another hereunder (collectively, "Confidential Information") shall be treated as confidential and not distributed to persons who are not bound by written confidentiality agreements to one of the Parties. If a party hereto receives a request for disclosure for any Confidential Information, such party shall promptly provide notice of such request to the other party. The party required to disclose Confidential Information shall only disclose such Confidential Information as advised by its legal counsel as legally required.
7. **Training.** County investigators and key research personnel shall fulfill County training requirements and provide documentation of such training, which shall be sufficient to meet the research requirements of UIC, before participating in any Research and County shall be responsible for assuring such fulfillment. The University shall cause UIC to provide training and continuing education to Principal Investigators eligible to conduct Research at County. No Research protocol will be accepted for review by the University until the University is assured that the Principal Investigator and key research personnel has satisfied County's training requirements.
8. **HIPAA Compliance.** The University and County shall each be responsible for assuring the compliance of its own employees and research under the "The Standards for Privacy of Individual Identifiable Health Information" (45 CFR Parts 160, 162 and 164) regulations ("HIPAA Regulations") and other applicable privacy regulations. County retains sole responsibility for reviewing and granting a HIPAA waiver or alteration when one is

requested. The UIC IRB can make a determination regarding the waiver or alteration, but only County has authority for making a final decision to grant the appropriate HIPAA waiver or alteration on behalf of the covered entity, and the County IRB shall serve as the Privacy Board (as defined under the HIPAA Regulations) for the Research.

9. **Conflict of Interest.** County will be responsible for the identification and management of all conflict of interest issues, real or perceived, with regards to the Research. Any disclosure and management of conflict of interest issues and all correspondences relating thereto shall be provided to the UIC IRB as promptly as practicable. County is responsible for the disclosure of its "Conflict of Interest Policy" and any amendments thereto to UIC IRB.

II. DOCUMENT RETENTION

1. The University shall retain all documents in connection with the review of any Research in accordance with its document retention policies and applicable federal and state laws, regulations and rules, and make such documents available to County upon its written request.
2. County shall retain copies of all submitted Research protocols, a copy of UIC IRB and County IRB approved consent documents, and all related correspondences and documentation, including, but not limited to, source documents such as patient medical records for the Research, in accordance with its documentation retention policies and applicable federal and state laws, rules and regulations. County will make such documents available to UIC upon its written request.

III. REPORTING

1. The University and County shall each report to the other immediately in writing any information regarding non-compliance in the Research, of which party becomes aware. Reports made by the University to County regarding such non-compliance in the Research shall be made to the Director of Human Subjects Protection at County. Reports made by County to the University regarding such non-compliance or violation in the Research shall be made to the Director of OPRS at UIC. As used in this Article III, non-compliance includes, but is not limited to, the breach of any law, regulation or institutional policy relating to research, including but not limited to, human subject protection, conflict of interest, or breach of research integrity.
2. The University and County shall report to the other immediately if any governmental or private oversight agency or organization initiates any action regarding non-compliance in any Research. Official responses to such alleged violations or misconduct will be led by and coordinated by County and the University (through UIC) jointly with the assistance and full cooperation of each party. In connection with any external review, inquiry, audit or any other action regarding non-compliance by any governmental or private oversight entity, the University and County will each make their respective Research records and any relevant documentation available to each other and to such entities. Each party shall cooperate with the other in good faith in any such review, inquiry, audit or other action and shall make their

personnel available to the other to the extent reasonably necessary and not unduly disruptive to the day to day business activities of such personnel.

3. The University and County shall immediately report to each other any unanticipated problem involving risks to subjects or others (UPIRSOs), any complaints from study subjects, serious adverse events (whether expected or unexpected, whether related or unrelated to research), the suspension or termination of activities with respect to any Research, or any other major protocol violations of which it becomes aware involving any Research. This obligation to report is in addition to, and in no way replaces, the Principal Investigator's duty to report adverse events, UPIRSOs or protocol violations as required by any contract, law, regulation, or policy. County shall be responsible for the enforcement of the response and determination of the UIC IRB with respect to any such problems, complaints, serious advents, or any other protocol violations.
4. On an annual basis, the University shall report to County the status and disposition of all Research.

IV. TERMINATION

Either party may terminate this Agreement immediately upon notice to the other party, if such party violates federal or state law, the respective institutional policies relating to research, or otherwise materially breaches this Agreement, and fails to cure such violation or breach after having received written notice of such breach from the other party and afforded thirty (30) days from the date of such notice to cure such breach or violation. In the alternative to termination, the non-breaching party shall have the sole discretion to continue this Agreement under such terms and conditions as it may find to be reasonably necessary to assure compliance with federal and state law. In the event that this Agreement is terminated, both parties will work in good faith to transfer all current UIC IRB approved Research to another institutional review board of record. In no event shall either party take any action which could harm or put at risk of harm any human research subjects.

V. LIABILITY AND INSURANCE

Neither party to this Agreement shall be liable for any negligent or wrongful act chargeable to the other unless such liability is imposed by a court of competent jurisdiction. This Agreement shall not be construed as seeking to either enlarge or diminish any obligation or duty owed by one party against the other or against third parties. In the event of a claim for any wrongful or negligent act, each party shall bear the cost of its own defense. The parties shall each maintain general and professional liability insurance covering their employees with minimum coverage levels of \$1,000,000 per occurrence and \$3,000,000 annual aggregate. The University shall also maintain (1) a directors and officers liability policy, and (2) an errors and omissions policy. Minimum coverage levels on each of the preceding policies shall be \$1,000,000 per occurrence and \$3,000,000 annual aggregate. Such insurance coverage may be either from a commercial carrier or reasonable self-insurance mechanism and verification will be provided upon request.

VI. MISCELLANEOUS

1. **Independent Contractor Relationship.** The Parties are each an independent contractor and not an agent or employee of the other. Neither party shall have the authority to make any representations or commitments of any kind that are binding on the other party, except as may be provided for in this Agreement or authorized by the other party in writing.
2. **Governing Law.** This Agreement shall be governed by Illinois law.
3. **Amendment and Waiver.** No amendment or waiver of any provision of this Agreement shall be binding on either Party unless consented to in writing by both. No waiver of any provision of this Agreement shall constitute a waiver of any other provisions, nor shall any waiver constitute a continuing waiver so as to impair either Party's rights, unless otherwise expressly provided in writing.
4. **Severability.** If any provision is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, such determination shall not impair or affect the validity, legality, or enforceability of the remaining provisions.
5. **Entire Agreement.** This Agreement, together with its attachments, if any, constitutes the entire agreement between the Parties with respect to its subject matter and supersedes all prior agreements, negotiations and discussions, whether written or oral. There are no conditions, agreements, representations, warranties or other provisions relating to the subject matter except as provided herein. Each party shall retain and make available to the United States Department of Health and Human Services a fully executed copy of this Agreement.
6. **Survival.** Article I Section 6, Article II, Article III Sections 1 to 3 inclusive, Article IV, Article V and this Article VI shall survive the termination or expiration of this Agreement.
7. **Debarment.** Each party hereto represent to the other that neither it nor any of its trustees, officers, directors, employees or agents have been debarred, suspended or excluded from participation in any state or federal healthcare program including, without limitation, Medicare, Medicaid or Tricare. Each party further represents that in the event it or any of its trustees, officers, directors, employees or agents are excluded from participation in a state or federal healthcare reimbursement program, unless such person is terminated from the entity or is no longer affiliated with the entity, this Agreement may be terminated immediately upon written notice by the other party.
8. **Notices.** All notices, consents and other communications hereunder shall be in writing and shall be deemed to have been duly given (a) when delivered by hand to; (b) on the next business day if sent by Federal Express or a similar overnight courier to; (c) five days after being deposited in any U.S. post office enclosed in a postage prepaid, registered or certified envelope addressed to; or (d) when successfully transmitted by telecopier (with a confirming copy of such communication to be sent as provided in clauses (a), (b) or (c) above) to, the party for whom intended, at the address or telecopier number for such party set forth below (or at such other address or telecopier number for a party as shall be specified by like

notice):

To the University:

University of Illinois at Chicago
Office of Protection of Research Subjects
Attention: Director
203 AOB, MC 672
1737 West Polk Street
Chicago, Illinois 60612
Telecopier: (312) 413-2929

To County:

Lisa Giordano, M.D., or her designee
Division of Pediatric Hematology/Oncology
Stroger Hospital of Cook County
1900 West Polk Street, 11th Floor
Chicago, Illinois 60612

9. **Interpretation.** The parties understand and acknowledge that they have each been represented by (or have had the opportunity to be represented by) counsel in connection with the preparation, execution and delivery of this Agreement. This Agreement shall not be construed against any party for having drafted it.
10. **Counterparts.** This Agreement may be executed in any number of counterparts, and each such counterpart hereof shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement.
11. **Headings.** The headings of the sections of this Agreement are inserted for convenience of reference only and shall not be considered a part thereof.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

The Board of Trustees of the University
of Illinois

Walter K. Knorr 12/16/08
Walter K. Knorr, Comptroller Date

Nichole M. Thompson 12/16/08
Nichole M. Thompson, Secretary Date

APPROVED AS TO FORM
[Signature] 12/18/08
OFFICE OF UNIV. COUNSEL

Cook County / Cook County Health and
Hospitals System

Todd Stroger Date
President, Cook County Board of
Commissioners

David Orr Date
Clerk of Cook County

Acknowledged By:

Maurice Lemon 1/14/09
Maurice Lemon, M.D. Date
Chief Medical Officer,
Stroger Hospital

Lisa Giordano MD 1/13/09
Lisa Giordano, M.D. Date
Division of Pediatric
Hematology/Oncology,
Stroger Hospital